IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	Confirmation No.: 4614
KOLTERMAN, Orville G. *et al.*	Art Unit: 1639
Appl. No.: 10/643,681	Examiner: LIU, Sue Xu
Filed: August 18, 2003	Atty. Docket: 254/057CON
For: METHODS FOR REGULATING GASTROINTESTINAL MOTILITY	

Response to Notice of Non-Compliant Amendment under 37 C.F.R. §1.121

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This communication is responsive to the Notice of Non-Compliant Amendment (37 C.F.R. § 1.121) dated July 13, 2007, in connection with the above-identified application. This response is being filed within one month of the mailing date of the Notice of Non-Compliant Amendment. Accordingly, this response is timely filed.

Amendments to the claims begin on page 2 of this paper.

Remarks begin on page 10 of this paper.

CERTIFICATE OF TRANSMITTAL UNDER 37 C.F.R. 1.8

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being electronically filed via EFS-Web at the United States Patent and Trademark Office, on the date shown below.

7/23/07
Date of Deposit

Deborah L. Wykes
Name of Person Mailing Paper

Signature of Person Mailing Paper

AMENDMENTS TO THE CLAIMS

Please enter the following amendments without prejudice or disclaimer. This listing of claims will replace all prior versions, and listings, of claims in the application.

In the claims:

1-23. (Canceled)

24. (Currently amended) A method of reducing or moderating a postprandial rise in plasma glucose in a mammal comprising administering to said mammal an amylin or an amylin agonist analogue in an amount effective to reduce or moderate a postprandial rise in plasma glucose, wherein the amylin agonist analogue is a peptide and binds to an amylin receptor.

25. (Currently amended) The method of claim 24 wherein the amylin agonist analogue has the following amino acid sequence: ~~[SEQ ID NO:40]~~

$^{1}A_1$-X-Asn-Thr-^{5}Ala-Thr-Y-Ala-Thr-^{10}Gln-Arg-Leu-B_1-Asn-^{15}Phe-Leu-C_1-D_1-E_1-$^{20}F_1$-G_1-Asn-H_1-Gly-^{25}Pro-I_1-Leu-Pro-J_1-^{30}Thr-K_1-Val-Gly-Ser-^{35}Asn-Thr-Tyr-Z **(SEQ ID NO:40)**

wherein

A_1 is Lys, Ala, Ser or Hydrogen;

B_1 is Ala, Ser or Thr;

C_1 is Val, Leu or Ile;

D_1 is His or Arg;

E_1 is Ser or Thr;

F_1 is Ser, Thr, Gln or Asn;

G_1 is Asn, Gln or His;

H_1 is Phe, Leu or Tyr;

I_1 is Ile, Val, Ala or Leu;

J_1 is Ser, Pro or Thr;

K_1 is Asn, Asp or Gln;

X and Y are independently selected residues having side chains which are chemically bonded to each other to form an intramolecular linkage, wherein said intramolecular linkage comprises a disulfide bond, a lactam or a thioether linkage; and Z is an amino, alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy; and provided that when A_1 is Lys, B_1 is Ala, C_1 is Val, D_1 is Arg, E_1 is Ser, F_1 is Ser, G_1 is Asn, H_1 is Leu, I_1 is Val, J_1 is Pro, and K_1 is Asn; then one or more A_1 to K_1 is a D-amino acid and Z is selected from the group consisting of alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy.

26. (Currently amended) The method of claim 24 wherein the amylin agonist analogue has the following amino acid sequence: ~~[SEQ ID NO:42]~~

$^{1}A_1$-X-Asn-Thr-^{5}Ala-Thr-Y-Ala-Thr-^{10}Gln-Arg-Leu-B_1-Asn-^{15}Phe-Leu-C_1-D_1-E_1-$^{20}F_1$-G_1-Asn-H_1-Gly-^{25}Pro-I_1-Leu-J_1-Pro-^{30}Thr-K_1-Val-Gly-Ser-^{35}Asn-Thr-Tyr-Z **(SEQ ID NO:42)**

wherein

A_1 is Lys, Ala, Ser or hydrogen;

B_1 is Ala, Ser or Thr;

C_1 is Val, Leu or Ile;

D_1 is His or Arg;

E_1 is Ser or Thr;

F_1 is Ser, Thr, Gln or Asn;

G_1 is Asn, Gln or His;

H_1 is Phe, Leu or Tyr;

I_1 is Ile, Val, Ala or Leu;

J_1 is Ser, Pro, Leu, Ile or Thr;

K_1 is Asn, Asp or Gln;

X and Y are independently selected residues having side chains which are chemically bonded to each other to form an intramolecular linkage, wherein said intramolecular linkage comprises a disulfide bond, a lactam or a thioether linkage; and Z is amino, alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy, and provided that

when

(a) A_1 is Lys, B_1 is Ala, C_1 is Val, D_1 is Arg, E_1 is Ser, F_1 is Ser, G_1 is Asn, H_1 is Leu, I_1 is Val, J_1 is Pro and K_1 is Asn; or

(b) A_1 is Lys, B_1 is Ala, C_1 is Val, D_1 is His, E_1 is Ser, F_1 is Asn, G_1 is Asn, H_1 is Leu, I_1 is Val, J_1 is Ser and K_1 is Asn;

then one or more of A_1 to K_1 is a D-amino acid and Z is selected from the group consisting of alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy.

27. (Currently amended) The method of claim 24 wherein the amylin agonist analogue has the following amino acid sequence: ~~[SEQ ID NO:44]~~

$^{1}A_1$-X-Asn-Thr-^{5}Ala-Thr-Y-Ala-Thr-^{10}Gln-Arg-Leu-B_1-Asn-^{15}Phe-Leu-C_1-D_1-E_1-$^{20}F_1$-G_1-Asn-H_1-Gly-$^{25}I_1$-J_1-Leu-Pro-Pro-^{30}Thr-K_1-Val-Gly-Ser-^{35}Asn-Thr-Tyr-Z **(SEQ ID NO:44)**

wherein

A_1 is Lys, Ala, Ser or hydrogen;

B_1 is Ala, Ser or Thr;

C_1 is Val, Leu or Ile;

D_1 is His or Arg;

E_1 is Ser or Thr;

F_1 is Ser, Thr, Gln or Asn;

G_1 is Asn, Gln or His;

H_1 is Phe, Leu or Tyr;

I_1 is Ala or Pro;

J_1 is Ile, Val, Ala or Leu;

K_1 is Asn, Asp or Gln;

X and Y are independently selected residues having side chains which are chemically bonded to each other to form an intramolecular linkage, wherein said intramolecular linkage comprises a disulfide bond, a lactam or a thioether linkage; and Z is amino, alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy; and provided that

when A_1 is Lys, B_1 is Ala, C_1 is Val, D_1 is Arg, E_1 is Ser, F_1 is Ser, G_1 is Asn, H_1 is Leu, I_1 is Pro, J_1 is Val and K_1 is Asn ~~[SEQ ID NO:41]~~ **(SEQ ID NO:41)**; then one or more of A_1 to K_1 is a D-amino acid and Z is selected from the group consisting of alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy.

28. (Currently amended) The method of claim 24 wherein the amylin agonist analogue has the following amino acid sequence: ~~[SEQ ID NO:45]~~

$^{1}A_1$-X-Asn-Thr-^{5}Ala-Thr-Y-Ala-Thr-^{10}Gln-Arg-Leu-B_1-Asn-^{15}Phe-Leu-C_1-D_1-E_1-$^{20}F_1$-G_1-Asn-H_1-Gly-^{25}Pro-I_1-Leu-Pro-Pro-^{30}Thr-J_1-Val-Gly-Ser-^{35}Asn-Thr-Tyr-Z **(SEQ ID NO:45)** wherein

A_1 is Lys, Ala, Ser or hydrogen;

B_1 is Ala, Ser or Thr;

C_1 is Val, Leu or Ile;

D_1 is His or Arg;

E_1 is Ser or Thr;

F_1 is Ser, Thr, Gln or Asn;

G_1 is Asn, Gln or His;

H_1 is Phe, Leu or Tyr;

I_1 is Ile, Val, Ala or Leu

J_1 is Asn, Asp or Gln;

X and Y are independently selected residues having side chains which are chemically bonded to each other to form an intramolecular linkage wherein said intramolecular linkage comprises a disulfide bond, a lactam or a thioether linkage; and Z is amino, alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy; and

provided that when A_1 is Lys, B_1 is Ala, C_1 is Val, D_1 is Arg, E_1 is Ser, F_1 is Ser, G_1 is Asn, H_1 is Leu, I_1 is Val and J_1 is Asn ~~[SEQ ID NO:41]~~ **(SEQ ID NO:41)**; then one or more of A_1 to J_1 is a D-amino acid and Z is selected from the group consisting of alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy.

29. (Currently amended) The method of claim 24 wherein said amylin agonist analogue is any one of $^{18}Arg^{25,28}Pro$-h-amylin ~~[SEQ ID NO:3]~~ **(SEQ ID NO:3)**, des-$^{1}Lys^{18}Arg^{25,28}Pro$-h-amylin ~~[SEQ ID NO:6]~~ **(SEQ ID NO:6)**, $^{25,28,29}Pro$-h-amylin ~~[SEQ ID NO:1]~~ **(SEQ ID NO:1)**, des-$^{1}Lys^{25,28,29}Pro$-h-amylin ~~[SEQ ID NO:10]~~ **(SEQ ID NO:10)**, $^{18}Arg^{25,28,29}Pro$-h-amylin ~~[SEQ ID NO:8]~~ **(SEQ ID NO:8)**, des-$^{1}Lys^{18}Arg^{25,28,29}Pro$-h-amylin ~~[SEQ ID NO:9]~~ **(SEQ ID NO:9)**, $^{25}Pro^{26}Val^{28,29}Pro$-h-amylin ~~[SEQ ID NO:7]~~ **(SEQ ID NO:7)**, or des-$^{1}Lys^{25}Pro^{26}Val^{28,29}Pro$-h-amylin ~~[SEQ ID NO:38]~~ **(SEQ ID NO:38)**.

30. (Currently amended) The method of claim 24 wherein the amylin agonist analogue is $^{25,28,29}Pro$-h-amylin ~~[SEQ ID NO:1]~~ **(SEQ ID NO:1)**.

31-37. (Canceled)

38. (Previously presented) The method of claim 24 wherein the mammal has diabetes.

39. (Previously presented) The method of claim 38 wherein the diabetes is type 1.

40. (Previously presented) The method of claim 38 wherein the diabetes is type 2.

41. (Previously presented) The method of claim 25 wherein the mammal has diabetes.

42. (Previously presented) The method of claim 41 wherein the diabetes is type 1.

43. (Previously presented) The method of claim 41 wherein the diabetes is type 2.

44. (Previously presented) The method of claim 26 wherein the mammal has diabetes.

45. (Previously presented) The method of claim 44 wherein the diabetes is type 1.

46. (Previously presented) The method of claim 44 wherein the diabetes is type 2.

47. (Previously presented) The method of claim 27 wherein the mammal has diabetes.

48. (Previously presented) The method of claim 47 wherein the diabetes is type 1.

49. (Previously presented) The method of claim 47 wherein the diabetes is type 2.

50. (Previously presented) The method of claim 28 wherein the mammal has diabetes.

51. (Previously presented) The method of claim 50 wherein the diabetes is type 1.

52. (Previously presented) The method of claim 50 wherein the diabetes is type 2.

53. (Previously presented) The method of claim 30 wherein the mammal has diabetes.

54. (Previously presented) The method of claim 53 wherein the diabetes is type 1.

55. (Previously presented) The method of claim 53 wherein the diabetes is type 2.

56. (Currently amended) The method of claim 24 wherein the amylin agonist analogue has the following amino acid sequence: ~~[SEQ ID NO:31]~~

$^{1}A_1$-X-Asn-Thr-^{5}Ala-Thr-X-Ala-Thr-^{10}Gln-Arg-Leu-B_1-Asn-^{15}Phe-Leu-C_1-D_1-E_1-$^{20}F_1$-G_1-Asn-H_1-Gly-$^{25}I_1$-J_1-Leu-K_1-L_1-^{30}Thr-M_1-Val-Gly-Ser-^{35}Asn-Thr-Tyr-Z **(SEQ ID NO:31)** wherein

A_1 is Lys, Ala, Ser, Hydrogen or acetylated Lys;

B_1 is Ala, Ser or Thr;

C_1 is Val, Leu or Ile;

D_1 is His or Arg;

E_1 is Ser or Thr;

F_1 is Ser, Thr, Gln or Asn;

G_1 is Asn, Gln or His;

H_1 is Phe, Leu or Tyr,

I_1 is Ala or Pro;

J_1 is Ile, Val, Ala or Leu;

K_1 is Ser, Pro, Leu, Ile or Thr;

L_1 is Ser, Pro or Thr;

M_1 is Asn, Asp or Gln;

X and Y are independently selected residues having side chains which are chemically bonded to each other to form an intramolecular linkage, wherein said intramolecular linkage comprises a disulfide bond, a lactam or a thioether linkage; and Z is an amino, alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy; and provided that

(a) when A_1 is Lys, B_1 is Ala, C_1 is Val, D_1 is His, E_1 is Ser, F_1 is Ser, G_1 is Asn, H_1 is Phe, I_1 is Ala, J_1 is Ile, K_1 is Ser, L_1 is Ser, and M_1 is Asn ~~[SEQ ID NO:46]~~ **(SEQ ID NO:46)**;

(b) when A_1 is Lys, B_1 is Ala, C_1 is Ile, D_1 is Arg, E_1 is Ser, F_1 is Ser, G_1 is Asn, H_1 is Leu, I_1 is Ala, J_1 is Ile, K_1 is Ser, L_1 is Pro, and M_1 is Asn ~~[SEQ ID NO:47]~~ **(SEQ ID NO:47)**;

(c) when A_1 is Lys, B_1 is Ala, C_1 is Val, D_1 is Arg, E_1 is Thr, F_1 is Ser, G_1 is Asn, H_1 is Leu, I_1 is Ala, J_1 is Ile, K_1 is Ser, L_1 is Pro, and M_1 is Asn ~~[SEQ ID NO:48]~~ **(SEQ ID NO:48)**;

(d) when A_1 is Lys, B_1 is Ala, C_1 is Val, D_1 is Arg, E_1 is Ser, F_1 is Ser, G_1 is Asn, H_1 is Leu, I_1 is Pro, J_1 is Val, K_1 is Pro, L_1 is Pro, and M_1 is Asn ~~[SEQ ID NO:41]~~ **(SEQ ID NO:41)**;

(e) when A_1 is Lys, B_1 is Ala, C_1 is Val, D_1 is His, E_1 is Ser, F_1 is Asn, G_1 is Asn, H_1 is Leu, I_1 is Pro, J_1 is Val, K_1 is Ser, L_1 is Pro and M_1 is Asn ~~[SEQ ID NO:43]~~ **(SEQ ID NO:43)**; or

(f) when A_1 is Lys, B_1 is Thr, C_1 is Val, D_1 is Arg, E_1 is Ser, F_1 is Ser, G_1 is His, H_1 is Leu, I_1 is Ala, J_1 is Ala, K_1 is Leu, L_1 is Pro and M_1 is Asp ~~[SEQ ID NO:49]~~ **(SEQ ID NO:49)**; then one or more of any of A_1 to M_1 is not an L-amino acid and Z is not amino.

57. (Previously presented) The method of claim 56 wherein the mammal has diabetes.

58. (Previously presented) The method of claim 57 wherein the diabetes is type 1.

59. (Previously presented) The method of claim 57 wherein the diabetes is type 2.

60-69. (Canceled)

REMARKS

In the Notice of Non-Compliant Amendment mailed July 13, 2007, the Examiner alleges that Claims 25-30 and 56 do not recite SEQ ID NOs as previously filed in the Response to Office Action received April 10, 2006. By the present communication, Applicants provide a claim set in full conformity with the amendments made in the Responses to Office Action dated April 5, 2006, and October 31, 2006, and with the amendment accompanying a Request for Continued Examination dated April 24, 2007. Applicants understand that provision herewith of only the corrected section of the allegedly non-compliant amendment will overcome the current Notice of Non-Compliant Amendment (Notice of Non-Compliant Amendment dated July 7, 2007, lines 32-37). Applicants further understand that the submission filed April 24, 2007, has been entered (Office Action accompanying Notice of Non-Compliant amendment dated July 13, 2007). Accordingly, the claim set provided herewith is a corrected claim set as filed with the Request for Continued Examination April 24, 2007.

In order to avoid any possible confusion with respect to SEQ ID NOs recited in the present claims, by the present amendment SEQ ID NOs in the claims which were originally enclosed in square brackets in the amendment dated April 5, 2006, have been replaced with SEQ ID NOs enclosed in parentheses after the indicated sequences. No new matter is introduced by the present amendments.

Accordingly, Claims 24-30 and 38-59 are pending and under active consideration in the instant application. The Listing of Claims with appropriate status identifier begins on page 2 of this communication. The amendment is made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover, have not acquiesced to any rejections or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

CONCLUSION

Applicants believe that all issues raised in the Notice of Non-Compliant Amendment have been properly addressed in this response. Furthermore, Applicants will respond to the Office Action accompanying the present Notice of Non-Compliant Amendment in due course.

If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

No additional fees are believed due for this submission. However, if an additional fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535 referencing Docket No. 254/057CON. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Date: July 23, 2007

Respectfully submitted,

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